EXHIBIT A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION NO. 2:12-md-02327** **MDL No. 2327**
This Document Applies To All Actions	:	Judge Joseph R. Goodwin

To: Christy D. Jones, Esq.
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PLAINTIFFS' FIRST INTERROGATORIES TO DEFENDANTS

Pursuant to Fed. R. Civ. P. 33, Plaintiffs in the above-referenced cases serve Defendants Johnson & Johnson, Ethicon, Inc., Ethicon SARL, Ethicon SAS, Ethicon LLC, Johnson and Johnson Medical LTD, Johnson and Johnson Medical GMBH (collectively, "Ethicon" and/or "Defendants"), with the following Interrogatories.

DEFINITIONS

1. The term "Pelvic Mesh", or "Pelvic Mesh Products" shall include any product advertised, analyzed, assembled, designed, developed, distributed, engineered, inspected, labeled, manufactured, marketed, packed, produced, promoted, processed, researched, sold and/or tested by Johnson & Johnson Inc., its predecessors in interest, subsidiaries, agents, representatives, servants and/or employees under the trade names Prolene mesh, Prolene Soft (PS), Prolift, Prolift +M, Prosima, TVT, TVT-Obturator, TVT-Secur, TVT-Exact, TVT-Abbrevo, TVT-Catheter Guide, TVT-Introducer, Gynecare TVT Family of Prodcuts, Gynecare TVT Retropubic System Tension-Free

Support for Incontinence, Gynecare Family of Products for Pelvic Floor Repair, in the United States, or any other trade name outside the United States. This shall also include any "kits" which contain any of these products, any components of these kits such as cannulas and trocars as well as any predecessor or successor products which are designed intended to be surgically used in pelvic floor repair or to treat urinary incontinence developed, in development, or marketed by Defendants.

2. "Hernia Mesh Products" is used to refer to any mesh product intended for use in hernia repair, developed, in development, or sold by Defendants.

3. Each of the terms "You", "Your", or "Defendant" refers to the defendant, Johnson & Johnson Inc., and Ethicon Inc., its predecessors in interest, subsidiaries, agents, representatives, servants and/or employees, and any predecessor or heritage entity to whom the attached "Requests for Production of Documents" is addressed and/or on whose behalf the response is being made. Where documents or other materials are requested, those materials are to be produced by You if in Your possession, custody, or control.

4. "Complication" refers to any injury or disorder occurring in a patient caused by or potentially caused by Pelvic Mesh including, but not limited to: bleeding or clotting disorders, bowel obstruction, bowel perforation, chronic pain, cystocele, death, discomfort, dyspareunia, fistulas, impaired sexual relations, infection, incontinence, inflammation, mesh erosion, mesh exposure, mesh extrusion, pain, pelvic organ prolapse, pelvic tumors or fibroids, peritonitis/sepsis, uretal obstruction, ureter obstruction, ureteral obstruction, urethral obstruction, urinary retention, vaginal or bladder infections, would

healing problems, and any other disease or disorder of the bowel, bladder, gut, intestines, uterus, or vagina.

5. "Other Pelvic Mesh Products" shall mean any products designed for and intended for use in the pelvic floor for the treatment of Stress Urinary Incontinence (SUI) or Pelvic Organ Prolapse (POP).

6. "Label" or "Labeling" refers to any draft or approved Product Insert, Patient Brochure, Instructions for Use (IFU), Final Printed Labeling, or any other documentation included in the prescription medication dispensed to patients, provided to surgeons, hospitals, or other physicians.

7. "Marketing" refers to any piece of material or collection of materials used to promote the use, sale, distribution, implantation or awareness of Pelvic Mesh Products includes, but is not limited to, public relations activities, press releases, talking points, junkets, physician training seminar materials, public statements, standby statements, posters, printed advertisements, video web postings, video advertisements, audio advertisements, internet advertisements and web postings, social media and twitter postings, news releases, promotional literature, public affairs material, product descriptions, product literature, books, medical journal articles, slim jims, notepads, calendars, office supplies, and all other such promotional materials.

8. "Study" or "Studies" refers to an examination, collection, compilation or analysis of data, including but not limited to product or event registries, controlled clinical trials, double-blind randomized trials, single-blind randomized trials, non-blinded trials, nonrandomized trials, experiments, meta-analyses, observational studies, prospective cohort studies, retrospective cohort studies, time series studies, case-

controlled studies, ecological studies, cross-sectional studies, superiority trials, non-inferiority trials, equivalence trials, crossover studies, pharmacological studies, and any other type of epidemiological analysis. This includes studies conducted in animals, humans, chemicals, health databases, or any other data source.

A request for information concerning a Study that has been completed should be construed as including the following documents: the protocol for the conduct of the test/study, and amendment(s) to the protocol, documents or databases containing the original raw study data, documents containing the written study report and all attachments thereto, any summary, abstract, analysis, compilation, including evaluation or interpretation of the study and all investigators or entities, facilities, firms, universities and/or laboratories involved in the testing.

9. "Test" or "Testing" refers to a procedure intended to establish the quality, performance, or reliability of a Pelvic Mesh Product, or one of its components, or a process concerning a Pelvic Mesh Product. "Testing" includes but not limited to product strength testing, toxicity testing, space of mesh openings (poreacity) testing, pigment testing, sterility testing, machine tolerance testing, engineering studies, machine testing, product absorption testing, durability testing, inertness testing, laser-cutting and machine-cut testing, and residual particle testing.

A request for information concerning a Test that has been completed should be construed as including the following documents: the protocol for the conduct of the test, and amendment(s) to the protocol, documents or databases containing the original raw test data, documents containing the written test report and all attachments thereto, any summary, abstract, analysis, compilation, including evaluation or interpretation of the test

and all persons or entities, facilities, firms, universities and/or laboratories involved in the testing.

10. "Manufacturing Defect" or "Defect" shall refer to a frailty or shortcoming in product resulting from a departure from its design specifications during production. This includes but is not limited to: items packaged incorrectly, items labeled incorrectly, items not cut to specifications, fraying or disintegration of products, pigment discoloration, defective components such as inserter springs, or any products that do not meet any engineering, design, or manufacturing specifications.

11. "Correspondence" shall mean any document or electronic message carried by the United States Postal Service, any private courier or courier service, telefax or telegraph, voice message, e-mail, internet posting, intranet posting, or tweet transferred or transmitted in any manner whatsoever.

12. "Person" shall mean and include any natural person, governmental body or agency, a corporation, partnership, foundation, joint venture firm, association, trust, or any other form of business or organizational entity.

13. "Document" shall mean every original and every non-identical copy (including blind copies) of each and every paper, writing, picture, photograph, internet posting, intranet posting, slide, tweet, movie, film, visual or audio transcription, video tape, sound recording, microfilm, data stored or recorded on or in punch cards, computer tapes, disc, reels, flash drives, smart phones, cloud storage, computer hard drives, portable hard drives, servers or other devices for business or machines or other means of storing and/or transmitting human intelligence, and any other printed or readable material, to be included without limitation in this definition of "document" are every

invoice, statement, bill, ledger sheet, recommendation, endorsement, order, discretion, letter, telegram, teletype, report, memorandum (including without limitation interoffice memoranda, file memoranda, work memoranda and memoranda of telephone conversations), interview, sketch, graph, chart, note (including without limitation notes used to prepare any letter, memorandum, reports or other documents as herein defined), contract, agreement, form, e-mail, messenger, worksheet, timesheet, expense ledger, check, (canceled or otherwise), check stub, voucher receipts, witness (including potential witness) statement, transcript, interview, sound recording transcription, computer printout, book of accounts, payroll record, minutes, diaries (both office and personal), log, file card, raw data, notes and/or travel report, data, meta-data, statement of expenses incurred, report of investigation, report of interview, record, brochure, book, exhibit, draft, certificate, table, price list and any other tangible item or think readable or visual material of whatever nature and every file folder, schema, and data map in which the above items are stored, filed or maintained.

14. "Concerning" shall mean relating in any way, in connection with, about, regarding, applying to, relevant to, involving, having to do with, referring to, implicating, dependent upon, pertinent to, or bearing upon.

15. "FDA" mean the United States Food & Drug Administration, any committee, subcommittee or advisory committee thereto, and any person, employee or agent thereof.

16. "Agency" means any agency, committee, subcommittee or advisory committee of any foreign or domestic government which bears responsibility or exercises authority over manufacture, distribution, labeling, sale and/or marketing of

medical devices or human health in any jurisdiction, and any employee or agent thereof. This includes, but is not limited to the European Medicines Agency (EMEA), the Therapeutic Goods Administration, (TGA), The Japanese Ministry of Health and Welfare, and the Chinese State Food & Drug Administration (SFDA).

17. "Under Your Control" means in the possession of or under the direction of You or any current or former agent or representative of You. If responsive material ever was under Your control buy You now contend that it is not under Your control, You are instructed to identify the material specifically, state its whereabouts and identify its custodian.

INSTRUCTIONS

1. In responding to these Interrogatories, please set forth the language of each request immediately prior to the response given for that request.

2. Please state any objections to a discovery request with specificity.

3. In answering the discovery requests, please furnish all information available to You and known by You, including any non-privileged information in Your possession or in the possession of Your agents and/or attorneys.

4. If any Document is produced in response to a discovery request below, identify the Document(s) by bates number in Your response to the discovery request.

5. If a Document was in Your possession, custody, or control and would be responsive to one of the below discovery requests but has been deleted or otherwise destroyed, please (a) describe the Document; (b) state the date(s) on which such item was deleted and/or destroyed; (c) Identify the Person who deleted or destroyed the item; and (d) describe the means, manner, and/or action taken to delete or destroy the item.

6. As used herein, the term "or" shall be understood to include "and" whenever such construction would make a phrase more, rather than less, inclusive and vice versa.

7. Regardless of the tense employed, all verbs shall be read as applying to past, present and future as is necessary to make any phrase more, rather than less, inclusive.

8. Where the name or identity of a person is requested, please state full name, home address and business address.

9. Where knowledge or information in possession of a party is requested, such request includes knowledge of the parties, agents, representatives and unless privileged, his attorneys. When answer is made by a corporate Defendant, agency, association or other entity other than an individual, state the name, address and title of the person supplying the information and making the affidavit or oath and the source of said information.

10. If you cannot answer after conducting a reasonable investigation, you should so state and answer to the extent you can, stating what information you do have, what information you cannot provide and stating what effort you made to obtain the unknown information.

11. Plaintiff requests that you produce the documents described herein below, whether the same is in your possession or subject to the control of you or any of your agents, employees, representatives, servants, accountants and/or attorneys.

12. Plaintiff requests that the documents requested herein below be produced in a file folder or other container in which they are maintained or stored, and that the

order of sequence of the documents, if more than one within a file is requested, be in the same order or sequence within such file as was maintained in the ordinary course of business just prior to the production thereof. Plaintiff demands that You produce all documents with the objective code (e.g., Bate Stamp number) utilized in the location, organization, or codification of the responses.

13. If all or any part of any discovery request is objected to as seeking privileged information, for each such objection provide the following information:

(a) the nature of the privilege asserted;

(b) the type of Document or Communication (*e.g.*, letter, memorandum, notes of meeting, conversations, etc.) and its title (if any);

(c) the date said Document or Communication was created or occurred;

(d) the length of the Document (in pages);

(e) the author or speaker and all recipients;

(f) the job title and business addresses of the author and all recipients; and

(g) the subject matter of the Document.

14. These discovery requests are continuing in nature and require supplemental answers in accordance with F.R.C.P. 26(e) in the event You or other persons acting on Your behalf become aware of additional information or Documents between the time Your answers are given and the time of trial that renders Your answers no longer correct, accurate, or complete.

INTERROGATORIES

1. If at any time you applied for, supplemented, or otherwise filed or responded to any Pelvic Mesh Product 510(k), add-to-file, 522 order, or any other regulatory submission, was there any information that was required by any regulation, law or rule to be provided to the FDA or any Foreign Agency that You did not provide, for that piece of information, please specifically set forth the following:

a. The specific type of information not provided;

b. The date the information should have been provided;

c. The date the information was first reported to You;

d. How You became aware of such information. (i.e., clinical trial, animal study, literature search, add-to file, etc.);

e. The name of anyone employed by You to whom the information was first reported;

f. Attach any and all documents relating to any of Your responses to this interrogatory.

ANSWER:

2. What warnings, information or notifications, if any, did you provide to health care providers and patients concerning the use and Complications of Pelvic Mesh Products.

Produce copies of any and all such warnings, information and notifications that relate to any of your responses.

ANSWER:

3. If during or after the time that you marketed, sold, distributed or produced Pelvic Mesh Products, You were aware of any complications or adverse events for which You did not provide warnings, information or notifications to health care providers, consumers, or any governmental agencies, please identify:

a. The complications or adverse events;

b. If the complication or adverse event was attributed to the Pelvic Mesh Product, the surgeon, both, or some other conclusion.

c. When the complication or adverse event was first reported to You;

d. How You became aware of complication, (i.e. clinical trial, study, literature search, etc.)

e. The name of anyone employed by You to whom it was first reported, and the name of the Person who reported it to You;

f. The identity of those individual(s) who made the decision whether or not to inform Health Care Providers, consumers, or governmental agencies of these complications or adverse events.

ANSWER:

4. If You have received any Communications (other than lawsuits filed in any jurisdiction or attorney claim letters) concerning the safety or complications from the use of Pelvic Mesh Products please identify:

a. the individual(s) and/or company(ies) or institution(s) who communicated with you, and if not in a written or reproductive format, describe the nature of such communication in detail.

b. Produce any communications responsive to this interrogatory.

ANSWER:

5. Please identify by name and date the Persons who authored and/or received any correspondence (other than lawsuits filed in any jurisdiction or attorney claim letters) concerning whether the Pelvic Mesh Products' Instructions for Use, (IFU's) patient brochures, or related information should be modified about the complications, risks and benefits, or indications concerning the Pelvic Mesh Products. Please produce copies of any communications responsive to this interrogatory.

ANSWER:

6. Provide the name and title of the Person employed by You who was primarily responsible for testing the safety, efficacy, sterility, and manufacturing standards of Pelvic Mesh Products for each year from 1999 to 2012.

ANSWER:

7. If You or any Person employed by You or on your behalf is currently performing any Testing or Studies on Pelvic Mesh Products and its potential association or causal relationship with Complications, please set forth specifically for each test or Study:

a. The start date of the study or test

b. The anticipated end-date of the study or test

c. The anticipated publication date of the study or test

d. The anticipated dates for the disclosure to the FDA or others of any preliminary data or results from the study (please specifically identify those persons or agencies to whom disclosure will be made);

e. The identity of the source of any funding for the study, in whole or in part, if the study is not wholly funded by You;

f. All endpoints of those studies;

g. documents concerning the studies you identified above;

h. The basis for the decision to perform such studies;

i. The identity of the persons employed by You who determined that such studies would be performed.

j. Attach any and all documents relating to any of Your responses to this interrogatory.

ANSWER:

8. Identify each advertising firm, public relations firm, marketing firm or medical communications company you engaged to draft studies, market and/or advertise Pelvic Mesh Products, including the identity of the manager of your accounts.

ANSWER:

9. Give the name, official capacity or position of those Persons employed or formerly employed by You who were responsible for communicating with the FDA and equivalent foreign Agencies Concerning Pelvic Mesh Products.

ANSWER:

10. Please state the name, address, phone number, official capacity and/or position, and a brief description of their job responsibilities, of those persons employed or

formerly employed by you who were responsible for or in charge of the following departments, between 1999 and the present:

a. Regulatory affairs/compliance;

b. Toxicity and pigment testing;

c. Engineering

d. Strength/Tensile strength testing;

e. Machining;

f. Porosity (space between mesh pores) testing;

g. Epidemiology and outcome studies;

h. Marketing;

i. Manufacturing;

j. Sales;

k. Safety and efficacy; and

l. Supply Chain Management;

m. Reporting of adverse events and complications.

ANSWER:

11. If You met or conferred with any Person, other than Johnson & Johnson, Inc. or Ethicon Inc. employees, to discuss whether there was an association or causal relationship between Pelvic Mesh Products and any Complications, please:

a. Identify the dates and attendees of each such meeting or communication;

b. Identify what was discussed or presented in connection with or during each meeting or communication;

c. Produce all documents relating to the meeting or communication.

ANSWER:

12. If during or after the time that you marketed, sold, distributed or produced Pelvic Mesh Products, You were aware of any Manufacturing Defects or Defects of any kind please identify:

a. The nature and extent of the Defect

b. The day you first became aware of the Manufacturing Defect;

c. The start date when the Defect occurred;

d. The date when the Defect was resolved

e. The dates of the disclosure to the FDA or other Agencies, if any

f. Whether or not there was a recall as a result of the Defect

g. The identity of the persons employed by You who determined that such Defects existed

h. Attach any and all documents relating to any of Your responses to this interrogatory.

ANSWER:

13. For each year from 1999 to the present, state the total number of employees You had in:

a. the sales and marketing departments

b. the regulatory and safety departments

ANSWER:

14. State the name(s), title, address and phone number of each individual who prepared or assisted in the preparation of these interrogatories.

ANSWER:

15. When did You acquire information that provided evidence of a reasonable association between Pelvic Mesh Products and any Complications.

ANSWER:

16. When did You acquire information that provided evidence of a causal association between Pelvic Mesh Products and any Complications.

ANSWER:

17. Please identify each electronic database (including but not limited to the name of the database, date ranges, size, data map/schema operating system and interface application) utilized by you concerning:

a. Adverse event reports or medical device reports;

b. Sales and sales training;

c. Marketing;

d. Regulatory compliance;

e. Key opinion leaders, preceptors, investigators, members of your speakers bureau and product champions;

f. Communications with physicians or other healthcare providers;

g. Studies;

h. Design Failure Mode and Effects Analyses;

i. Risk assessment or analysis;

j. Design changes;

k. Record retention;

l. Complaints or reports of injuries; and

m. Trending of adverse events.

ANSWER:

18. For each of the Pelvic Mesh Products, please identify all testing you conducted, sponsored or funded concerning the:

a. Measurement or the potential for and amount of *in vivo* (human or animal) shrinkage;

b. Measurement or the potential for and amount of *in vivo* (human or animal) creep;

c. Measurement or the potential for and amount of *in vivo* (human or animal) physical or mechanical changes;

d. Measurement or the potential for and amount of physical or mechanical forces in the human female pelvic floor;

e. Measurement or the potential for and amount of anticipated stresses in the human female pelvis;

f. Measurement or the potential for and amount of *in vivo* (human and animal) movement due to the body's reaction to the mesh;

g. Determination of a physician or other healthcare provider's proper course of action in the event of any failure or malfunction *in vivo* (human or animal).

h. Human tissue elastic properties, including such properties in the human female pelvis; and

i. Human or animal pelvis.

ANSWER:

19. Please state whether any of your pelvic mesh products are not suitable for any particular patient populations. For each such patient population, please state:

a. The specific patient population for which your pelvic mesh product is not suitable, and the reasons why these products are not suitable for the particular patient population;

b. When you became aware that such patient population was not an appropriate candidate for your pelvic mesh product(s);

c. The date and manner in which you conveyed this information to physicians and/or patients;

d. What actions you took to ensure that patients in the particular patient populations did not receive the pelvic mesh product.

ANSWER:

20. Please identify each individual involved in the decision to cease market withdrawal of any of your pelvic mesh products, and the precise reasons that you

withdrew each such product from the market.

ANSWER:

21. For each of your pelvic mesh products, provide the specific dates of use for each of the following items:

a. Instructions for Use

b. Directions for Use

c. Patient Brochures

d. Sales training materials

e. Physician training material

f. Direct to Consumer Advertising

g. Sales aids, physician leave behinds and physician marketing materials.

ANSWER:

22. Please state when YOU first became aware of the criminal investigation of Ethicon, Inc. related to YOUR Pelvic Mesh Products and/or Hernia Mesh Products and identify any and all employees who were involved with that or any other criminal investigation related to YOUR conduct in the area of Pelvic Mesh Products and/or Hernia Mesh Products.

ANSWER:

PLAINTIFFS' CO-LEAD COUNSEL

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PLAINTIFFS' CERTIFICATE OF SERVICE OF FIRST INTERROGATORIES TO DEFENDANTS

I hereby certify that on July 25, 2012, I served Plaintiff's First Interrogatories to Defendants via email and the foregoing document was electronically filed with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

By: ____/s/Thomas P. Cartmell_____

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